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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,043	04/12/2004	Barrie Tan	BT-001	4102

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EXAMINER	
MCCORMICK EWOLDT, SUSAN BETH	
ART UNIT	**PAPER NUMBER**
1661	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,043	TAN ET AL.	
	Examiner	Art Unit	
	S. B. McCormick-Ewoldt	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,25,26,28-30 and 37-50* is/are pending in the application.

4a) Of the above claim(s) *25,26 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 37-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 27, 2006 has been entered.

Status of Application

The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1661.

Election/Restrictions

Applicant elected, without traverse, Group I and the species, palm extract, in the reply filed on July 21, 2005.

Previously submitted claim 26 and 28-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 26 and 28-30 are drawn to a previously withdrawn method. Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26 and 28-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims Pending

Applicant has cancelled claims 2-24, 27 and 31-36. Applicant has added claims 37-50. Claims 1, 25 and 37-50 will be examined on the merits and solely in regards to the elected species. Claims 26 and 28-30 are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is over the amounts of tocotrienols and tocopherols "≥50% of the tocotrienols," "tocotrienols are ≥60% and tocopherols are ≤15%." and "tocotrienols are ≥80% and "≤5% tocopherols." The specification (i.e. see [0053]) does not disclose appropriate "equal to" (i.e. ≥ and ≤) of tocotrienols and tocopherols amounts as stated in the claims. Thus, an attempt to limit specific amount of tocotrienols and tocopherols adds new matter. The specification does not disclose the specific amount of tocotrienols and tocopherols; thus, these limitations may introduce new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 47 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In claims 39, 47 and 49, the recitation "natural extract" is indefinite because it is not clear what is encompassed by this recitation. Clarification is needed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Tan *et al.* (US 6,350,453).

Tan *et al.* (US 6,350,453) expressly teaches that *Bixa orellana* (i.e. annatto) seed components which is a byproduct oil (column 5, lines 51-55) contain tocotrienols which includes delta-tocotrienols and gamma-tocotrienols (column 2, lines 4-6, 18-20, 45-49). The tocotrienol extracted by Tan *et al.* meet the limitations of claim 1 as the composition comprises tocotienol extracts of *Bixa orellana* (i.e. annatto) oil byproduct and thus anticipates the claimed invention.

Claims 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Tan *et al.* (US 6,350,453).

Tan *et al.* (6,350,453) expressly teaches a *Bixa orellana* (i.e. annatto) oil byproduct (column 5, lines 51-55) and a natural extract (i.e. vegetable oil) is added and thru a distillation process tocotrienols are 20-90% (column 4, lines 33-37; column 5, lines 30-42). Tan teaches that there is essentially no tocopherol present in this distillate (column 2, lines 46-48). The tocotrienol extracted by Tan *et al.* meet the limitations of claim 47 as the composition comprises tocotienol extracts of *Bixa orellana* (i.e. annatto) oil byproduct and a natural extract and thus anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 25, 37-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tan (US 6,350,453) in view of Wright (US 5,217992) in view of Meijer *et al.* (US 6,787,151).

Tan (US 6,350,453) disclose that a *Bixa orellana* (i.e. annatto) oil byproduct (column 5, lines 51-55) and a natural extract (i.e. vegetable oil) is added and thru a distillation process tocotrienols are 20-90% by weight (column 4, lines 33-37; column 5, lines 30-42). Tan teaches that there is essentially no tocopherol present in this distillate (column 2, lines 46-48). In addition, Tan discloses tocopherols and tocotrienols act as antioxidants and tocotrienols have been documented to possess hypocholesteromic effects and to be useful in the treatment of cardiovascular disease and cancer (column 1, lines 10-46).

Tan does not disclose wherein the amounts are disclosed for the tocotrienols and tocopherols or wherein palm oil is specifically use together with the Bixa orellana extract.

Wright (US 5,217992) discloses that palm oil is a rich source of tocotrienols such as gamma-tocotrienols and delta-tocotrienols, which are known to treat hypercholesteremia, hyperlipedemia an thromboembolic disorders (column 1, lines 12-15; column 3, lines 21-27; column 4, lines 23-33).

Meijer *et al.* (US 6,787,151) disclose that phytosterols and soy protein are well documented to have a hypocholesterolmic effect (column 1, lines 29-30 and 39-41). In addition, other ingestable materials as causing improvement in cholesterol status include niacin, tocotrienols, chromium, soy, lecithin and chitosan (column 2, lines 43-49).

One of ordinary skill in the art would have been motivated to combine *Bixa orellana* (i.e. annatto) oil byproduct and a palm oil extract (i.e. natural extract) because of the beneficial properties that tocotrienols have in decreasing blood levels and the various types of tocotrienols would be inherent to the extract. It was clear from the Tan reference that *Bixa orellana* (i.e. annatto) oil byproduct and a natural extract (i.e. vegetable oil) is added together and thru a distillation process, tocotrienols amounts are 20-90% by weight. Tan also discloses that there is essentially no tocopherol present in this distillate. In addition, Tan discloses tocopherols and tocotrienols act as antioxidants and tocotrienols have been documented to possess hypocholesteromic effects and to be useful in the treatment of cardiovascular disease and cancer It was further clear from the Wright reference that palm oil is a rich source of tocotrienols, such as gamma-tocotrienols and delta-tocotrienols, which are known to treat hypercholesteremia, hyperlipedemia an thromboembolic disorders. It was further clear from the Meijer reference that phytosterols and soy protein are well documented to have a hypocholesterolmic effect and other ingestable materials to cause improvement in cholesterol status include niacin, tocotrienols, chromium, soy, lecithin and chitosan. It would clearly have been obvious to one of ordinary skill in the art to adjust the amounts of tocotrienols and tocopherols as taught by the cited reference because the references clearly disclose that such preparations is intended to be administered so as to achieve the therapeutic effect beneficially disclosed by the references. The adjustment of particular conventional working conditions (e.g., determining a result-effective amount) is deemed merely a matter of judicial selection and routine optimization, which is well within the purview of the skilled artisan.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions to treat hypocholesteromic effects. It is well known that

it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re* Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re* Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re* Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions for treating hypocholesteromic effects, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions decreasing treat hypocholesteromic effects. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition because of the beneficial properties that tocotrienols contain. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re* Sussman, 1943 C.D. 518; *In re* Huellmantel 139 USPQ 496; *In re* Crockett 126 USPQ 186.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the cited reference.

Therefore, one of ordinary skill in the art would have had a reasonable expectation that Bixa orellana byproduct and palm oil and phytosterols, soy proteins, niacin, tocotrienols, chromium, soy, lecithin and chitosan can be combined in a composition which would treat hypocholesteromic effects and contain the various type of tocotrienols. Based on this reasonable expectation of success, a person of ordinary skill in the art would be motivated to modify the teachings of the references.

Summary

No claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTOPHER R. TATE
PRIMARY EXAMINER